

REMARKS/ARGUMENTS

In response to the Office Action mailed October 9, 2009 Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, claim 1 is amended, claims 9 -11 have been cancelled without prejudice and no claims have been added, so that claims 1 and 6-8 are currently pending. No new matter has been entered.

Claims 1 and 6-7 and 9-11 were rejected as being unpatentable over US 2003/0065382 to Fischell et al. (Fischell) in view of WO 03/082368 to Hossainy et al. (Hossainy), U.S. Patent Application No. 2002/0004679 to Eury et al. (Eury) and WO 96/34003 to Shull et al. (Shull). Claim 8 was rejected as being unpatentable over Fischell, Hossainy, Eury, Shull and US Patent Application No. 2003/0065346 to Evens et al. (Evens). These rejections are respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

The present invention claims a medical device comprising an implantable structure; a basecoat matrix, including a combination of rapamycin and a topoisomerase I inhibitor, in therapeutic dosages, incorporated in a first polymeric material, the basecoat matrix being affixed to the surface of the implantable medical

device; and a topcoat, including a second polymeric material, affixed to the basecoat matrix for controlling the elution rate of the rapamycin and the topotecan, the topotecan being present in a concentration of about seventy-five nanomolar to about three-hundred nanomolar, wherein the first polymeric material comprises a fluoropolymer comprising polyvinylidene fluoride and hexafluoropropylene in a sixty/forty weight ratio and the second polymeric material comprises a chemically incompatible polymer comprising polybutylmethacrylate.

Fischell discloses a stent coated with a number of polymers, a number of drugs, including sirolimus. The drugs may be on the surface of the polymer or mixed in with the polymer. Hossainy discloses 40-O-(3-hydroxy)propyl-rapamycin plus a polymer and a barrier layer. Eury discloses a stent coated with a topoisomerase inhibitor for treating restenosis. The stent may be fabricated from a polymer loaded with topotecan plus other drugs. Shull discloses the use of various analogs of camptothecin. Evens discloses anastomosis devices having polymer coatings with drugs contained therein.

The references taken as a whole fail to disclose or even suggest a medical device with two specific drugs in a specific dosage in a two distinct polymer structure with a specific polymer ratio. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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